NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHLKLINE, Defendant.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 08-cv-3706 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motions by Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") for a judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) and to dismiss Count II of the Complaint pursuant to Fed. R. Civ. P. 12(b)(6). After carefully considering all submissions, and based upon the following, it is the finding of this Court that GSK's motion for a judgment on the pleadings is **granted** and GSK's motion to dismiss Count II of the Complaint is **denied** as moot.

I. BACKGROUND[1]

A. Factual Background

This dispute arises from a settlement agreement between GSK and Plaintiffs Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals USA, Inc. (collectively "Teva") that resolved

[1] The facts set forth in this Opinion are taken from the parties' respective papers.

patent litigation between the parties concerning the drug lamotrigine, which GSK has marketed under the brand name Lamictal®. Until this year, GSK was the sole supplier of lamotrigine. In 2002, Teva filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") for approval to market a generic product equivalent to GSK's Lamictal tablets. GSK responded by suing Teva for patent infringement. Teva replied by, among other things, challenging the validity of GSK's lamotrigine patent. After a bench trial was held on this matter the parties entered into a settlement, which is memorialized in several documents, including a Settlement Agreement and a License Agreement, both dated February 16, 2005. On April 4, 2005, the parties submitted a Stipulation and Order of Dismissal which officially resolved the litigation. In total, the complete agreement between the parties (the "2005 Agreement") includes the Settlement Agreement, the License and Supply Agreement, and the Stipulation and Order of Dismissal. The Settlement Agreement states, "this Settlement Agreement is the product of negotiation and preparation by the Parties and their respective attorneys." The Settlement Agreement and the License and Supply Agreement provide that they "shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania without regard to its conflict of laws principles."

The License Agreement grants to Teva a right to sell generic lamotrigine from July 21, 2008, six-months prior to when it otherwise would have been able to. The parties made clear that this right was exclusive—including as to GSK and its affiliates. Sections 2.3(a) and (b) of the License Agreement provide that:

> GSK hereby grants Teva (and its Affiliates) an exclusive (even as to GSK and its Affiliates and Third Parties with respect to Generic Equivalents) non-transferable (or otherwise nonassignable or non-sublicensable) waiver, with respect to [Teva's ANDA filings] any Pediatric Exclusivity granted for Lamotrigine to GSK (or its Affiliate).

"Generic Equivalent" is defined in Section 1.1 of the License Agreement to mean:

> on a product by product basis, any (i) FDA approved (for the avoidance of doubt, not a tentative approval) prescription generic Lamotrigine tablet product (in either 25mg, 100mg, 150mg or 200mg strength, as the case may be) for human use that is A Rated to, or supplied or manufactured by or for GSK (or its Affiliates) under NDA No. 20-241 for sale in the Territory as a generic equivalent to, the applicable 25mg, 100mg, 150mg, or 200mg strength of GSK's Lamictal® (Lamotrigine) tablets approved under GSK's NDA No. 20-241. . . . For the avoidance of doubt, Generic Equivalent shall not include any Product sold under GSK's Lamictal® or Lamictal XR trademark, or other trademarks owned or controlled by GSK (or its affiliates).

Just prior to Teva launching its generic, GSK approached various pharmacies, group purchasing organizations, and long-term care facilities and proposed that they purchase and distribute GSK's Lamictal at a generic product price which would be eligible for generic product reimbursement. GSK expressly directed in its written proposals that the distributors were to dispense Lamictal under the "DAW5" code during the term of the agreement.

DAW codes are "dispense as written" codes that inform a pharmacy what kind of product to dispense. Increasingly, DAW codes dictate what kind of reimbursement the pharmacy may receive from managed care organizations and state Medicaid programs. in order to contain costs such programs often prohibit pharmacies from prescribing branded products where a generic is available. "DAW5" is a code that signifies that a branded product is permissibly being dispensed at a generic price. If a pharmacy uses the DAW5 code, it will be reimbursed the amount usually reimbursed for the generic, even though it actually dispensed a branded product. In order to get its customers to agree to use a DAW5 code for Lamictal, GSK promised to make the pharmacies whole for the losses that such a practice would cause by giving discounts on various GSK products.

B.____Procedural Background

Teva filed its Complaint on July 23, 2008. In its Complaint, Teva alleges two claims arising from the 2005 Agreement, Count I Breach of Contract and Count II Breach of Contract - Good Faith and Fair Dealing. On October 6, 2008, GSK responded to the two Counts in Teva's Complaint by:

(1) an Answer and Counterclaim directed to Count I; and (2) a motion to dismiss for failure to state a claim directed to Count II. The relevant portions of the 2005 Agreement have been attached by GSK to its Answer and are thus part of the pleadings in this action.

On November 3, 2008, Teva opposed GSK's motion to dismiss. GSK filed its reply brief in connection with its motion to dismiss on November 10, 2008.

On November 11, 2008, Teva Answered GSK's Counterclaim. In its Third Party Answer Teva admitted that the License and Supply Agreement is a binding contract that does not limit GSK's ability to set or change the price of Lamictal.

II. LEGAL STANDARDS

A. Motion For Judgment On The Pleadings

Fed. R. Civ. P. 12(c) allows a party to move for judgment on the pleadings "after the pleadings are closed – but early enough not to delay trial." Courts apply the same standard on a motion for judgment on the pleadings as on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). See Spruill v. Gillis, 372 F. 3d 218, 223 n.2 (3d Cir. 2004); Fed. R. Civ. P. 12(h)(2). Thus, in deciding a Fed. R. Civ. P. 12(c) motion, courts must accept all factual allegations in the complaint as true and view them in the light most favorable to the plaintiff. See NXIVM Corp. v. Sutton, 2007 WL 1876496 at *5 (D.N.J. June 27, 2007). A court however, need not "credit bald assertions or legal conclusions improperly alleged in the complaint." Cryofab, Inc. v. Precision Medical, Inc., 2008 WL 2705007, at *1 (D.N.J. July 08, 2008) (citing In re Burlington Coat Factory Sec. Litig., 114 F. 3d 1410, 1429 (3d Cir. 1997)). In Bell Atlantic Corp. v. Twombly, the Supreme Court established new language for pleading standards by holding that a plaintiff was required to plead "enough facts to state a claim to relief that is plausible on its face." 550 U.S. 544, 570 (2007). The "[f]actual allegations [of the

complaint] must be enough to raise a right to relief above the speculative level." Id. at 555. Nonetheless, the Supreme Court specified that there is no heightened standard of fact pleading or requirement to plead specifics. Id. at 570.

While the pleading standard as provided by Fed. R. Civ. P. 8 does not require "detailed factual allegations," it does demand more than an unadorned accusation. Id. at 555. A pleading that offers labels and conclusions or "a formulaic recitation of the elements of a cause of action will not do." Id. The Supreme Court explains:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of entitlement to relief."

Ashcroft v. Iqbal, 129 S. Ct. 1937 (U.S. 2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556-57, 570 (2007).

B. Elements of Breach of Contract

A breach of contract claim in Pennsylvania must be established by demonstrating the following three elements: "'(1) the existence of a contract, including its essential terms, (2) a breach of duty imposed by the contract, and (3) resultant damages.'" Gazarov v. Diocese of Erie, 80 Fed. Appx. 202, 206 (3d Cir. 2003) (quoting Williams v. Nationwide Mut. Ins. Co., 750 A. 2d 881, 884 (Pa. Super. Ct. 2000). While ambiguous writings are interpreted by the finder of fact, unambiguous contracts are interpreted by the court as a matter of law. See Panetta v. SAP America, Inc., No. 05-4511, 2007 WL 1001889, at *3 (E.D. Pa. March 30, 2007) (quoting Ins. Adjustment Bureau, Inc. v. Allstate Ins. Co., 588 Pa. 470, 905 A. 2d 462, 468-69 (Pa. 2006)). "When the terms of a contract are clear and

unambiguous, the intent of the parties is to be ascertained from the document itself." See id. In such cases, "a court should look to the four corners of the document and its express language." See Hazleton Area School Dist. v. Bosak, 671 A. 2d 277, 282 (Pa. Cmwlth. 1996) (citing Rusiski v. Pribonic, 511 Pa. 383, 515 A. 2d 507, 510 (Pa. 1986).

III. DISCUSSION

The pertinent facts in this case are not in controversy and the pleadings phase of this litigation is closed. GSK does not deny that it sold Lamictal under the DAW5 code. At issue here is whether selling Lamictal under the DAW5 code changes the product from being a name brand product to a "Generic Equivalent?"

The definition of "Generic Equivalent" is provided in the 2005 Agreement. In fact, as Teva admitted in its opposition to GSK's motion to dismiss Count II of the Complaint, the final sentence of the definition was added for clarification. This sentence specifies, "[f]or the avoidance of doubt, Generic Equivalent shall not include any Product sold under GSK's Lamictal® or Lamictal XR trademark, or other trademarks owned or controlled by GSK (or its Affiliates)." This last sentence clearly allows GSK to sell Lamictal as it sees fit. To this end, GSK came to an arrangement with some of its customers to sell Lamictal under a DAW5 code, however, the product being sold was still Lamictal.

The Court points out that the parties could have addressed DAW coding in the 2005 Agreement but did not. For the Court to now find that changing the DAW coding of Lamictal was prohibited by the 2005 Agreement would go against traditional practice because such a finding would expand the terms of the contract beyond their express meaning. See Hazleton Area School Dist., 671 A. 2d at 282 (under Pennsylvania law "a court should look to the four corners of the document and its express

language"). Looking at the agreement as a whole, it appears that the parties intended to prohibit GSK from developing a new trademark for lamotrgine that it would sell as a generic. It is evident that the parties intended to allow GSK to sell Lamictal as it saw fit. Teva seeks to impede GSK from using a highly effective method of competing with its generic product, however, competition between Teva's generic and Lamictal is precisely what the 2005 Agreement envisioned and authorized.

Moreover, as Teva details in its brief, the DAW5 code is specifically for brand name drugs and not for generics. If GSK used a code that is only available for generic drugs then Teva could have argued that GSK had changed the nature of Lamictal or wrongfully classified it as a generic. This is not the case, GSK used a tool for brand name drugs that was known at the time of the adoption of, and not prohibited by the 2005 Agreement.

Teva has not established a breach of the 2005 Agreement. The duty Teva is trying to enforce is that GSK cannot develop a generic of lamotrgine. GSK did not develop a generic trademark therefore, it has not breached the relevant duty. As a result, Teva has not and cannot establish a necessary prong of a breach of contract claim, namely breach of a duty. Therefore, GSK is entitled to a judgement on the pleadings. Moreover, because Teva has failed to state a claim upon which relief can be granted, the Complaint as to both Counts I and II is **dismissed**.

As a procedural matter, the Court must address GSK's Counterclaims. By way of its Counterclaims GSK seeks four types of relief. They are: (1) Dismissal of Teva's Complaint, with prejudice; (2) A declaration that the 2005 License & Supply Agreement between Teva and GSK does not restrict GSK's right to sell lamotrigine products under GSK's Lamictal® or Lamictal XR trademark at the price of its choice; (3) A Declaration that GSK's sale of lamotrigine products under GSK's Lamictal® or Lamictal XR trademark is not the sale of a "Generic Equivalent" under the 2005 License & Supply Agreement; and (4) An award of attorney's fees and costs.

GSK's requests for declaratory judgment and dismissal of Teva's Complaint are moot given that the Court has dismissed Teva's Complaint. The Court declines to consider GSK's request for attorney's fees and costs because Teva's Complaint was not so unreasonable or frivolous that granting attorney's fees or costs would be warranted. Therefore, GSK's Counterclaims are **dismissed**.

IV. CONCLUSION

Based on the foregoing, GSK's motion for a judgment on the pleadings pursuant to Fed R. Civ. P. 12(c) is **granted**; GSK's motion to dismiss Count II of Teva's Complaint is **denied** as moot; and GSK's Counterclaims are **dismissed**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: June 16, 2009
Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
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